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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/813,950	03/03/1997	MANFRED ASSMUS	583-252-0-PW	4092

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EXAMINER	
SELLERS, ROBERT E	

ART UNIT	PAPER NUMBER
1712	

DATE MAILED: 12/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

AS

Office Action Summary	Application No.	Applicant(s)	
	08/813,950	ASSMUS ET AL.	
	Examiner	Art Unit	
	Robert Sellers	1712	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *25-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *25-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The first Assmus declaration filed June 21, 1999 "is not effective for showing unexpected results because it does not provide a comparison with the claimed invention, i.e., in none of the tests was the melt temperature within the appellants' 100-150°C range (Board of Appeals affirmation rendered October 25, 2002, page 9, footnote 4)."

The supplemental declaration of Assmus filed October 5, 1999 was deemed to be unpersuasive in the Board of Appeals affirmation for the reasons espoused on pages 9-11. The melt-mixing temperature of 65°C is not representative of the closest prior art value of 100°C for Yajima et al. (cols. 5-7, Examples 4, 7 and 13) as well as 95°C and 100°C for Deleuil et al. (col. 5-6, Table 1, Tests 1-5) wherein the 100°C value is within the claimed range of from 100-150°C.

The microphotographs were considered to be inconclusive (page 10, line 14 to page 11, line 4):

> "The photographs and the results in the table, however, merely show that the polymer particles are smoother when the melt temperature is 150°C. The appellants have not established that polymer particle smoothness correlates with melt homogeneity. The appellants argue that separate phases indicate melt homogeneity (reply brief, page 2), but the photographs show that the polymer particles obtained using all of the melt temperatures are in a separate phase. Moreover, the polymer particles obtained using a melt temperature of 100°C are as similar to the particles obtained using a melt temperature of 65°C as they are to the particles obtained using a melt temperature of 150°C, especially when the flow improver is PEG 6000, GMS or stearic acid."

The evidence was not deemed to be commensurate in scope with the claims because a great variety of thermoplastic acrylic polymers and relative amounts of glycerol monostearate are used, yet only one thermoplastic acrylic polymer and either 50 wt% or 80 wt% of glycerol monostearate (currently outside of the claimed maximum of 50 wt%) are tested. The Board of Appeals found "no reasonable basis for concluding that the great number of materials encompassed by the appellants' claims would behave as a class in the same manner as the particular materials tested (page 11, lines 14-17)."

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Drugs Made in Germany article by Petereit et al.

The ground of rejection is changed from 35 U.S.C. 102(b) since the body of the abstract does not single out glycerol monostearate as a tabletting excipient which is identified in the last IT, lines 9-10.

The rejection is maintained for the reasons of record set forth in the previous Office action. The arguments filed November 18, 2003 have been considered but are unpersuasive.

The abstract describes pharmaceutical "particles . . . coated with aq. dispersions of methacrylic acid and methacrylic ester copolymers (Eudragit RL 30 D, RS 30 D, L 30 D055 and NE 30 D) . . . " It is then stated that "[a]dmixt. of 25-50% of tabletting excipients as microcryst. cellulose, sorbitol, starch and Na caroboxymethyl starch as fillers, and disintegrants were necessary . . ." The document clearly makes a distinction between the Eudragit copolymers and the tabletting excipients, fillers and disintegrants as additives which embrace glycerol monosterate.

It would have been obvious to utilize glycerol monostearate as a tabletting excipient, filler and/or disintegrant in order to provide "fast disintegration of the tablets, filling of the interspace, and/or separation and protection of the coated particles during compression.

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yajima et al.

The rejection is maintained for the reasons of record set forth in the previous Office action. The arguments filed November 18, 2003 have been considered but are unpersuasive.

Example 4 (col. 5) shows an amount of glycerol monostearate of 23.0% by weight (333 g of complex x 600 g/1000 g of glycerol monostearate per complex = 199.8 g of glycerol monostearate. 199.8 g + 667 g of other components = 866.8 g of total components. 199.8 g of glycerol monostearate ÷ 866.8 g of total components = 23.0% by weight of glycerol monostearate).

Based on the concentration of 23.0% by weight of glycerol monostearate relative to Eudragit® E thermoplastic acrylic plastic, the glass transition temperature (Tg) of the mixture is inherently no more than 20°K below the Tg of the Eudragit® E (*In re Fitzgerald*, 205 USPQ 594, CCPA 1980 and MPEP §§ 2112-2112.02). The burden of proof rests with applicants to contraindicate that the inherent Tg of the mixture of Yajima et al. falls outside of the claimed maximum of 20°K.

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deleuil et al.

The rejection is maintained for the reasons of record set forth in the previous Office action. The arguments filed November 18, 2003 have been considered but are unpersuasive.

The claims do not require an amount of glycerol monostearate solely relative to the acrylic plastic but merely requires from 20-50 wt % of glycerol monostearate which is shown in columns 5-6, Table 1, Tests 1-5 of Deleuil et al.

Column, lines 42 and 43-44 differentiate between glycerol palmitostearate and "the glycerol stearate marketed under the mark Precirol." Pollinger et al. (col. 6, lines 20-21) identifies Precirol as "mixtures of mono-, di- and trimesters of palimitic and stearic acid with glycerol." The Chemical abstracts assigns two different Precirol tradenames to glycerol esters wherein glycerol stearate is Precirol Special WL 2155 or Precirol WL 2155 (Chemical abstracts registry no. 11099-07-3), and glycerol palmitostearate is Precirol or Precirol R (Chemical abstracts registry no. 8067-32-1).

Since Deleluil et al. affirmatively designates glycerol stearate, the full Precirol tradename employed in Tests 1-5 is the Precirol (Special) WL 2155 which is glycerol monostearate.

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Burguiere et al. in view of Mueller et al.

The rejection is maintained for the reasons of record set forth in the previous Office action. The arguments filed November 18, 2003 have been considered but are unpersuasive.

The Board of Appeals affirmation on page 3, the last paragraph, establishes the equivalency between the disclosure of melt extrusion at from 50-200°C of Mueller et al. (col. 1, line 62 to col. 2, line 16) and the claimed "hot-melt liquid state at a temperature of 100-150°C." Page 7, the last paragraph of the decision confirms the propriety of relying upon Mueller et al. to teach melt extrusion as a means of formulating the acetylsalicylic acid microcapsule particles of Burguiere et al. in order to avoid the use of solvents, elaborate mixing processes, and demixing of the components; to minimize the number and amounts of auxiliaries; and to enable the preparation of a fixed solution along with a continuous process with high throughput and small losses (Mueller et al., col. 1, lines 36-46).

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staniforth et al. in view of Mueller et al.

The rejection is maintained for the reasons of record set forth in the previous Office action. The arguments filed November 18, 2003 have been considered but are unpersuasive.

Staniforth et al. espouses a combination of a sustained release carrier (col. 5, line 9) such as an aminoalkyl methacrylate copolymer (col. 18, lines 23, 24 and 27) and a surfactant such as glycerol monostearate (col. 11, line 33) at a quantity of as much as 20% by weight (col. 13, lines 37-39). The disclosure of myriad other permutations of the sustained-release formulation of the reference does not mitigate the recitation of the components and amount of surfactant within the claimed ambit.

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Japanese Patent No. 51-91317, Rudnic et al. and Pollinger et al. in view of Petereit et al., Burguiere et al. and Mueller et al.

The rejection is maintained for the reasons of record set forth in the previous Office action. The arguments filed November 18, 2003 have been considered but are unpersuasive.

It is acknowledged that the abstract of the Japanese patent does not recite a content of glycerol monostearate. Rudnic et al. does not show glycerol stearate at a proportion within the claimed limits, although there is no restriction as to its amount within the composition.

It would have been obvious to employ the glycerol monostearate of the Japanese patent, Rudnic et al. and Pollinger et al. within the proportion range of from 25-50% by weight of Petereit et al. in order to impart fast disintegration of the tablets, and as much as the 20% of Burguiere et al. in ordere to optimize the flow properties which are characteristic of plasticizers.

Regardless of whether Pollinger et al. denigrates cationic polymers, the Eudragit® NE 30 D (col. 5, line 27) is a thermoplastic acrylic plastic within the claimed realm. The affirmative recitation of glycerol monostearate (col. 5, lines 49 and 53) renders establishes its efficacy within the pharmaceutical microcapsule irrespective of whether or not it is exemplified.

Based on the equivalent thermoplastic acrylic plastics and glycerol monostearate utilized in the concentrations taught by Petereit et al. and Burguiere et al., Tg's of the acrylic copolymer/glycerol monostearate blends of the Japanese patent, Rudnic et al. and Pollinger et al. are inherently no more than 20°K below the Tg of the acrylic copolymers (*In re Fitzgerald*, 205 USPQ 594, CCPA 1980 and MPEP §§ 2112-2112.02). The burden of proof rests with applicants to validate that the inherent Tg of the blends of the patents lie outside of the claimed maximum of 20°K.

Claims 25-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mueller et al. in view of Petereit et al. and Burguiere et al.

The rejection is maintained for the reasons of record set forth in the previous Office action and the rebuttals presented hereinabove in response to the arguments filed November 18, 2003.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Monday to Friday from 9:30 to 6:00 EST

Robert Sellers
Primary Examiner
Art Unit 1712

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11/24/03